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10/807,369

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EXAMINER

WRIGHT, PATRICIA KATHRYN

ART UNIT

PAPER NUMBER

1797

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/807,369

Applicant(s)

YANAGAWA, TATSUYA

Examiner

P. Kathryn Wright

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-16 is/are pending in the application.
- 4a) Of the above claim(s) 8-9, 11-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-7 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. This Official action is in response to papers filed October 23, 2007 in which claims 1, and 3-7 were amended, claim 2 was canceled, claims 8-9 were withdrawn, and claims 10-16 were added. The amendments have been thoroughly reviewed and entered.

Claims 1, 3-16 are currently pending.

Election/Restrictions

1. Applicant's election of Group I (original claims 1-7) in the reply filed on October 23, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Newly submitted claims 11-16 are directed to an invention that is distinct from the invention originally claimed for the following reasons:

I. Claims 1, 3-7, 10 drawn to an automatic analyzer apparatus, classified in class 422, subclass 67.

III. Claims 11-13, drawn to a method of using an automatic analyzer apparatus, classified in class 436, subclass 43.

IV. Claims 14-16, drawn to an automatic analyzer apparatus, classified in class 422, subclass 64.

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3. Inventions I and IV are directed to related inventions (i.e., automatic analysis apparatus). The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed can have a materially different design, mode of operation, function, or effect, specifically, group IV requires the analysis result to be calculated, without interrupting measurement, using one of the analytical information pieces corresponding to any reagent lots which is not required in group I. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

4. Inventions III and [I,IV] are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process of group III as claimed can be practiced by hand.

5. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, newly added claims 8-9, 11-16 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 3-7 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claim 1 now recites "an error handling *processing device*". Claim 5 recites "an error *handling device*". The Examiner cannot find support for these new devices. Furthermore, Applicant has not pointed out where the claim limitations are supported in the specification. The specification does describe at the paragraph bridging pages 5 and 6, an automatic analysis apparatus that has an *error handling function* to calculate the analysis result based on pre-obtained analytical information corresponding to the reagent lot and to add a caution mark to the analysis result to

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attract attention, when the reagent lot information is not read out successfully. The error handling function is not an error handling *processing device* or an error *handling device*.

Thus, there does not appear to be adequate written description of the claim limitations "error handling processing device" and "an error handling device" in the application as filed. See MPEP 2163.04(I).

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 3-7 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As discussed above, independent claim 1 now recites "an error handling processing device" and claim 5 recites "an error handling device". It is not clear from the specification what the difference is between the "error handling *processing device*" and "error handling device".

New claim 10 recites the step of registering "the plurality of analytical information pieces". This lacks antecedent basis in the claim. Furthermore, it is not clear from the claim or the specification what elements correspond to the "analytical information pieces".

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1, 3, 5-6, and 10, as best understood, are rejected under 35

U.S.C. 102(b) as being anticipated by Saito et al. (EP 0 562 425 A1), hereinafter "Saito".

Saito teaches an analysis apparatus 2 for spotting a sample on the dry analysis element (analysis slide 10 and slide package) and analyzing the sample for its composition by measurement and calculation based on analytical information corresponding to the element information. The analysis apparatus of Saito comprises a reading device (bar code reading means and magnetic code reading means) for reading out element information attached to a dry analysis element (col. 10, lines 46+). The element information attached to the analysis element includes at least reagent lot information for correcting reagent-lot-specific variations (see col. 7, lines 5-40) to produce a lost specific standard curve.

Furthermore, the analysis apparatus of Saito has an error handling processing device or error handling device (both read on processing program) which has the

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function to calculate the analysis result based on pre-obtained analytical information (fixed information; col. 7, lines 14+) corresponding to the reagent lot and add a caution mark (alarm signal; see col. 10, lines 26+) to attract attention when the reagent lot information is not read out successfully (i.e., different reagent lot information is used).

With respect to claims 1, 5 and 10, any method step performed by the error handling processing device or error handling device, such as calculating the analysis result based on pre-obtained analytical information (fixed information; col. 7, lines 14+) corresponding to the reagent lot and add a caution mark to attract attention when the reagent lot information is not read out successfully, is not attributed patentable weight in the context of a claim addressed to physical hardware. Such method steps are only an intended usage of the hardware, not a limitation of the hardware itself.

With respect to claims 3 and 6, any method steps performed by the error handling processing device is not attributed patentable weight in the context of a claim addressed to physical hardware. Such method steps are only an intended usage of the hardware, not a limitation of the hardware itself. Nevertheless, Saito teaches a re-calculation function to re-calculate the analysis result when normal reagent lot information is input to correct the analysis result to which the caution mark was added. That is, the assay device of Saito can produce a lot-specific standard curve.

13. Claims 1, 3, 5-6 and 10, as best understood, are rejected under 35 U.S.C. 102(e) as being anticipated by Hiramatsu et al. (US 2004/0086429), hereinafter "Hiramatsu".

Hiramatsu teaches an analysis apparatus for spotting a sample on the

dry analysis element (test piece) and analyzing the sample for its composition by measurement and calculation based on analytical information corresponding to the element information. The analysis apparatus of Hiramatsu comprises a reading device 8 for reading out element information attached to a dry analysis element (col. 10, lines 46+). The element information 32 attached to the analysis element includes at least reagent lot information for correcting reagent-lot-specific variations, see para. [0060]. Furthermore, the analysis apparatus of Hiramatsu also has an error handling function (processing program) to calculate the analysis result based on pre-obtained analytical information corresponding to the reagent lot and add a caution mark (warning message; see para. [0107]) to attract attention when the reagent lot information is not read out successfully (i.e., measurement is past expiration date).

With respect to claims 1, 5 and 10, any method step performed by the error handling processing device or error handling device, such as calculating the analysis result based on pre-obtained analytical information (fixed information; col. 7, lines 14+) corresponding to the reagent lot and add a caution mark to attract attention when the reagent lot information is not read out successfully, is not attributed patentable weight in the context of a claim addressed to physical hardware. Such method steps are only an intended usage of the hardware, not a limitation of the hardware itself.

With respect to claims 3 and 6, any method steps performed by the error handling processing device is not attributed patentable weight in the context of a claim addressed to physical hardware. Such method steps are only an intended usage of the hardware, not a limitation of the hardware itself. Nevertheless, Hiramatsu teaches a re-

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calculation function to re-calculate the analysis result when normal reagent lot information is input to correct the analysis result to which the caution mark was added.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 4 and 7, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Saito (EP 0 562 425 A1) or Hiramatsu (US 2004/0086429), in view of Lappe (US Patent No. 5,902,982).

The teachings of Saito and Hiramatsu have been summarized previously, *supra*. Saito and Hiramatsu teach the element information in the form of a bar code, not an array pattern of dots.

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Lappe discloses an assay card having a machine readable assaying indicia located on a surface of the card. Lappe discloses the assay card 10 may be provided by a substrate 20 having assaying indicia 32a (bar code) and 32b (dot array pattern), see lines 1-67, col. 4, figs. 1-4C. Lappe further discloses that the appearance of the indicia of the present invention, including identification code or assaying indicia, may be provided in many contemplated optical forms. These forms include other patterns that are optically very different in appearance to those illustrated in FIGS. 2A, 3A, and 3B (lines 24-36, col. 7).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to utilize on the assay device of Saito or Hiramatsu the indicia in the form of a dot array pattern, as taught by Lappe, in order to provide information to a suitable apparatus which is not "human readable"; thus, not subject to interpretation and possible unauthorized dissemination (see col. 1, lines 19+ of Lappe).

Response to Arguments

17. Applicant's arguments filed October 23, 2007 have been fully considered but they are not persuasive. Regarding the previous rejection of claims 1-3, and 5-6 under 35 U.S.C. 102(b) as being anticipated by Saito (EP 0 562 425 A1), Applicant argues that while Saito does teach generating an alarm, Saito allegedly does not teach adding a caution mark to the analysis result to attract attention when the reagent lot information is not read out successfully.

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The Examiner respectfully disagrees with Applicant's argument. As discussed above, Saito teaches a processing program which calculates the analysis result based on pre-obtained analytical information (fixed information; col. 7, lines 14+) corresponding to the reagent lot. The processing program of Saito adds a caution mark (alarm signal; see col. 10, lines 26+) to attract attention when the reagent lot information is not read out successfully (i.e., different reagent lot information is used). Claim 1 states the caution mark is added to the analysis to *attract attention*. It is the Examiner's position that the alarm signal of Saito reads on "the caution mark", since the alarm generates a sound to *attract attention*. There is nothing in the claim or specification which would distinguish the limitation "caution mark" from an alarm signal. Therefore, this rejection is maintained.

Similarly, with respect to the previous rejection of claims 1-3, and 5-6 under 35 U.S.C. 102(e) as being anticipated by Hiramatsu et al. (US 2004/0086429), Applicant argues that while Hiramatsu issues a warning when certain read input data differs from an expected value, Hiramatsu allegedly does not teach adding a caution mark to the analysis result to attract attention when the reagent lot information is not read out successfully.

Again the Examiner disagrees with Applicant's assertions. The analysis apparatus of Hiramatsu has an error handling function (processing program) to calculate the analysis result based on pre-obtained analytical information corresponding to the reagent lot. The program adds a caution mark (warning message; see para.

[0107]) to attract attention when the reagent lot information is not read out successfully, that is, when the measurement is past expiration date.

It is the Examiner's position that the warning message of Hiramatsu reads on "the caution mark", since the message visually *attracts attention*. There is nothing in the claim or specification which would distinguish the limitation "caution mark" from a message. Therefore, this rejection is maintained.

Conclusion

18. No claims allowed.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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pkw


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